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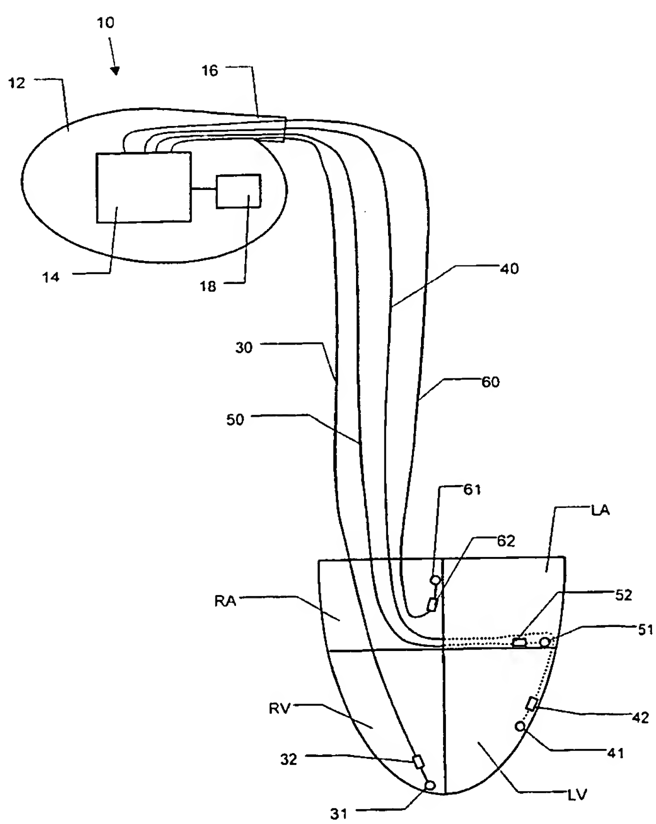
(54) Title: AN IMPLANTABLE HEART STIMULATING DEVICE, A SYSTEM INCLUDING SUCH A DEVICE AND A MANNER OF USING THE SYSTEM



(57) Abstract: The invention concerns an implantable heart stimulating device (10) comprising, inter alia, a control circuit (14) adapted to enable at least the following: a) delivering electrical stimulating pulses to the two ventricles (RV, LV) of a heart with a variable time interval (ΔT) between the pulses; b) sensing signals receivable from electrodes (31, 32; 41, 42; 51 , 52; 61, 62) positionable at two different positions in the heart, c) deriving an impedance value (Z) based on said sensed signals, d) determining a minimum value (Z_{min}) and a maximum value (Z_{max}) of said impedance value (Z) during a heart cycle, e) determining a relationship between said minimum (Z_{min}) and maximum (Z_{max})values, f) varying said time interval (ΔT) and monitoring said relationship over a plurality of heart cycles, g) setting said time interval (ΔT) such that said relationship fulfils a predetermined requirement. The invention also concerns a system including such a heart stimulating device (10) as well as a manner of using such a system.

WO 03/051457 A1

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An implantable heart stimulating device, a system including such a device and a manner of using the system

BACKGROUND OF THE INVENTION

1. Field of the invention

The present invention relates to an implantable heart stimulating device, a system including such a device and a manner of using the system. More precisely, the invention concerns such a stimulating device which comprises a housing and a control circuit arranged in the housing. The heart stimulating device is designed such that it can be used to stimulate both the ventricles of a heart.

2. Description of the prior art

Most heart stimulating devices, or pacers, are arranged to stimulate the right ventricle of the heart. It is also known to stimulate the left ventricle. In particular for the treatment of congestive heart failure (CHF) or other severe cardiac failures, it is known to stimulate the left ventricle, or both ventricles, in order to optimise the hemodynamic performance of the heart.

US-A-5 720 768 describes different possible electrode positions in order to stimulate or sense the different chambers of the heart.

In different kinds of heart stimulating devices it is also known to use an impedance value in order to control different pacing parameters.

US-5-154 171 describes the use of impedance values to control the pacing rate. The pacer described in this document is only arranged to stimulate the right side of the heart.

US-A-6 070 100 describes that electrodes may be positioned in both the left and the right atrium as well in the left and the right ventricle. The document describes the possibility of sensing the im-

pedance between different electrodes. The sensed impedance values may be used to improve the cardiac output.

US 2001/0012953 A1 describes bi-ventricular pacing. An impedance may be measured between electrodes on the right and the left sides of the heart. The variation of the impedance with time is detected. The detected impedance variation may be used in order to synchronise the contraction of the ventricles.

US 2001/0021864 A1 describes different manners of using the proximal and distal electrodes of different leads in order to inject a current and to measure an impedance. The measured impedance value may be used in order to maximise the cardiac flow.

For a patient suffering from congestive heart failure (CHF) it is of a great benefit to be able to increase the cardiac output, thereby decreasing the degree of CHF. One cause of CHF is that the left and right ventricles are not synchronised with each other. By optimising the synchronisation between the ventricles, the filling of the ventricles and the cardiac output may be increased.

SUMMARY OF THE INVENTION

A purpose of the present invention is to provide an implantable heart stimulating device which is able to deliver stimulating pulses to both the ventricles of a heart and which is able to control the delivery of the stimulating pulses such that the cardiac output is improved. A further purpose is to provide such a device which uses an impedance measurement in order to control the delivery of the stimulating pulses. A further purpose is to provide such a device which is able to improve the heart condition for a patient suffering from CHF. A still further purpose is to provide such a device which automatically finds an optimal time interval between stimulating pulses to the two ventricles. Another purpose is to provide such a device which in a relatively simple manner is able to automatically deliver the stimulating pulses in an optimal way. According to the

invention, also a system including such a device and a manner of using the system are provided.

The above purposes are achieved by an implantable heart stimulating device comprising:

a housing

a control circuit arranged in said housing, the control circuit being adapted to be connected to a first electrode to be positioned to stimulate a first ventricle of the heart,

said control circuit also being adapted to be connected to at least a second electrode to be positioned to stimulate the second ventricle of the heart,

said control circuit being arranged to at least enable the following:

a) delivering electrical stimulating pulses to said first and second electrodes in order to stimulate the first and second ventricles, respectively, the control circuit being arranged to enable the delivery of the said stimulating pulses to said first and second electrodes within the same cycle of the heart such that there is a time interval (ΔT) between them, the control circuit being arranged such that said time interval (ΔT) is variable,

b) sensing signals receivable from electrodes positionable at two different positions in the heart,

c) deriving an impedance value based on said sensed signals, said impedance value being indicative of the impedance between said electrodes positionable at two different positions in the heart,

d) determining a minimum value and a maximum value of said impedance value during a heart cycle,

e) determining a relationship between said minimum and maximum values,

f) varying said time interval (ΔT) and monitoring said relationship over a plurality of heart cycles,

g) setting said time interval (ΔT) such that said relationship fulfils a predetermined requirement.

It should be noted that the time interval (ΔT) may also be chosen to be equal to zero, i.e. in this case stimulation signals are delivered simultaneously to the first and second electrodes. Furthermore, it should be noted that the time interval (ΔT) may be positive or negative, i.e. the first electrode may emit stimulating pulses before or after the second electrode. In a practical use of the device, the sensed signals may be derived from electrodes positioned on different sides of the left ventricle. By monitoring the impedance value between such electrodes, an indication of the volume of blood in the left ventricle may be obtained. Said minimum and maximum values depend on the maximum and minimum, respectively, of the amount of blood in the ventricle. By determining said relationship and by setting the time interval (ΔT) such that the relationship fulfils a predetermined requirement, the delivery of the stimulating pulses to the first and second electrodes can be optimised in order to improve the cardiac output. In this manner, for example the heart condition of a patient suffering from CHF may be improved.

According to a preferred embodiment of the invention, said control circuit is arranged such that said relationship comprises the ratio between said minimum value and said maximum value. If the electrodes between which the impedance value is derived are suitably positioned, said ratio is closely linked to the so-called ejection fraction (EF). It has been found to be advantageous to use this ratio for controlling the delivery of the stimulating pulses.

According to another embodiment of the invention, said control circuit is arranged such that said relationship comprises the difference between said minimum value and said maximum value. Also this difference can function as an indication of the cardiac output and may therefore also be advantageously used for controlling the delivery of the stimulating pulses.

According to a further embodiment of the invention, said control circuit is arranged such that said relationship comprises the ratio between said minimum value and the difference between said minimum value and said maximum value. This particular ratio is even

closer linked to the EF if the electrodes between which the impedance value is derived are suitably positioned in relation to the heart. It should be noted that preferably, the ratio here refers to the absolute value of the division between the minimum value and said difference, since if the difference is negative the ratio would otherwise be negative. It is therefore preferably the magnitude of the ratio which is being referred to.

According to a further embodiment of the invention, said predetermined requirement is that said ratio is minimized. By minimising the ratio it has been found that an optimal cardiac output can be achieved. It should be noted that minimising the ratio is of course the same as maximising the inverse of the ratio. This possibility is thus included in the definition of minimising the ratio in this document.

According to still a further embodiment of the invention, said control circuit is arranged such that said time interval (ΔT) is changed in a first direction, said first direction being either an increase or a decrease of said time interval (ΔT), wherein the control circuit is arranged to monitor the change of said ratio when said time interval (ΔT) is changed in said first direction, wherein, if said ratio decreases, said time interval is further changed in said first direction until said predetermined requirement has been established. This has been found to be an advantageous embodiment for finding the time interval (ΔT) at which the predetermined requirement is fulfilled. For example, in this manner the minimum of the mentioned ratio may be established.

According to a further embodiment of the invention, the control circuit is arranged such that if said ratio increases, said time interval is changed in the opposite direction to said first direction, whereafter said time interval is further changed in said opposite direction until said predetermined requirement has been established. Through this embodiment, it is established that the time interval is changed in the correct direction such that the predetermined requirement may be established in an efficient manner.

According to still another embodiment of the invention, said control circuit is arranged also to enable the reception of signals indicating the activity level of a living being into which the heart stimulating device is implanted, wherein the control circuit is arranged such that at least the steps f) and g) are performed at a time when said signals indicate a low level of activity. Preferably, the optimal time interval (ΔT) is thus established while the patient in question is at rest. This is made possible by this embodiment, according to which the control circuit is also able to detect the level of activity of the living being in question.

According to a further embodiment of the invention, said control circuit is arranged to enable the delivery of stimulating pulses in which at least one atrio-ventricular delay (AV) is controllable, wherein said control circuit is arranged to keep said time interval (ΔT) at said set value and to:

h) vary said atrio-ventricular delay (AV) and to thereby monitor said relationship over a plurality of heart cycles,

i) set said atrio-ventricular delay (AV) such that said relationship fulfils said predetermined requirement. Since the device is arranged in this manner, the output of a heart can be further improved.

According to another embodiment of the invention, the heart stimulating device is arranged such that said control circuit is arranged to be connected to a first lead comprising said first electrode and a second lead comprising said second electrode, wherein said control circuit is arranged such that said sensed signals, receivable from electrodes positioned at two different positions, are received via said first and second leads, respectively. The heart stimulating device may thus for example be provided with a connector portion via which the control circuit may be connected to two different leads. Such leads may be positioned at different positions in relation to the heart. It is thereby possible to derive the impedance value between selected positions.

The above objects of the invention are also achieved by a heart stimulating system comprising a heart stimulating device according to any of the preceding embodiments and a first lead comprising at least said first electrode and a second lead comprising at least said second electrode, wherein said first and second leads are connected to the heart stimulating device such that said first and second electrodes are connected to said control circuit. The system thus comprises the two leads connected to the heart stimulating device. With such a system the above mentioned advantages may be achieved.

According to a preferred embodiment of said system, the system is arranged such that said impedance value is sensed between an electrode of said first lead and an electrode of said second lead. The leads may be positioned at suitable positions in relation to the heart. A suitable impedance value may thereby be derived between electrodes of the first and second lead, respectively.

The objects of the invention are also achieved by a manner of using a heart stimulating system according to any of the above embodiments, wherein said first electrode is positioned to stimulate a first ventricle of a heart of a human or animal being and said second electrode is positioned to stimulate the second ventricle of said heart and wherein the steps a) to g) are performed. According to this manner, the device is thus actually used to stimulate the two ventricles of a heart. Through this manner, the advantages described above in connection with the device may be achieved.

According to a preferred manner of using the system, said impedance value is sensed between two electrodes positioned such that the impedance value is measured across at least a part of one of said first and second ventricles. Through this manner of using the system, an indication of the amount of blood in the ventricle may be derived by said impedance value. The variation of this impedance value may be used as an indication of the amount of blood pumped by the ventricle.

According to a preferred manner of using the system, said ventricle, across which the impedance value is measured, is the left ventricle of the heart. To monitor the ejection fraction of the left ventricle is particularly important when for example treating a patient suffering from CHF.

According to a further manner of using the system, an impedance value is sensed across at least a part of the left atrium of said heart. Also the variation in the amount of blood in the left atrium may be used to control the heart stimulating device.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig 1 shows schematically a heart stimulating device connected to leads with electrodes positioned in a heart.

Fig 2 shows a flow chart of the function of the heart stimulating device according to one embodiment.

Fig 3 shows schematically the variation of the impedance with time.

Fig 4 shows schematically how a relationship between Z_{min} and Z_{max} depends on a time interval ΔT.

Fig 5 shows a flow chart of the function of the heart stimulating device according to an embodiment for adjusting the AV-delay.

DESCRIPTION OF PREFERRED EMBODIMENTS

An embodiment of the invention will now first be described with reference to Fig 1. Fig 1 thus schematically shows an implantable heart stimulating device 10. The heart stimulating device 10 is hereinafter also called a pacer. Such a heart stimulating device 10 is well known to a person skilled in the art and will therefore not be described in all its details here. The pacer 10 comprises a housing 12. A control circuit 14 is arranged in the housing 12. The pacer 10

includes a connector portion 16 to which a plurality of leads 30, 40, 50, 60 may be attached.

A first lead 30 comprises a distal electrode 31 (also called tip electrode) and a proximal electrode 32 (also called ring electrode). In the shown embodiment the lead 30 is thus bipolar. However, it is also possible that one or more leads are unipolar, i.e. that it only comprises one electrode. The lead 30 includes electrical conductors (not shown) through which the electrodes 31, 32 are connected to the control circuit 14. The control circuit 14 is also adapted to be connected to a second lead 40, which has corresponding electrode surfaces 41, 42.

The pacer 10 may also be arranged such that it is connectable to further leads. Fig 1 shows a third lead 50 with electrode surfaces 51, 52 and a fourth lead 60 with electrode surfaces 61, 62.

The control circuit 14 is arranged to emit stimulating pulses to different electrodes and also to sense signals received from the electrodes. The manner of arranging the control circuit 14 in order to perform the emission of pulses and the sensing is known to a person skilled in the art and will therefore not be shown in more detail here.

Fig 1 also schematically shows a heart comprising a right atrium RA, a right ventricle RV, a left atrium LA and a left ventricle LV. In the illustrated embodiment the electrodes 31, 32 are positioned in a conventional manner near the apex of the right ventricle RV. The lead 40 is positioned such that the electrodes 41, 42 may be used for emitting stimulating pulses to the left ventricle LV. The lead 40 may for example be introduced through the right atrium RA, via the coronary sinus into the middle or great cardiac vein. In the shown embodiment a third lead 50 is introduced such that the electrodes 51, 52 are positioned in the coronary sinus, a fourth lead 60 is introduced such that the electrodes 61, 62 are positioned in the right atrium RA in a conventional manner.

The control circuit 14 is arranged such that it may deliver stimulating pulses to both ventricles RV, LV, for example to the electrodes 31 and 41. The control circuit 14 is thus arranged such that stimulating pulses to the electrodes 31, 41 may be delivered within the same cycle of the heart (within the same heartbeat) with a time interval ΔT between the pulses to the electrodes 31 and 41. The control circuit 14 is arranged such that this time interval ΔT is variable. The time interval ΔT is sometimes also called the VV-interval. The control circuit 14 is also arranged such that it may sense signals receivable from the different electrodes and such that an impedance value Z is derived based on sensed signals, the impedance value Z being indicative of the impedance between electrodes at two different positions of the heart. For example, the impedance may be measured between the electrodes 31, 32 of the first lead 30 and the electrodes 41, 42 of the second lead 40. The impedance value Z may be derived in different manners described in for example the above cited documents. According to a preferred embodiment, a current is injected between electrodes 31 and 41 and the impedance value is measured between the ring electrodes 32, 42. It should be noted that it is also possible to derive an impedance value Z between other electrodes, for example between the electrodes 31, 32 of the first lead 30 and the electrodes 51, 52 of the third lead 50. Another possible impedance value is the impedance between the electrodes 51, 52 of the third lead 50 and the electrodes 61, 62 of the fourth lead 60.

The control circuit 14 is arranged such that it can determine a minimum value Z_{min} and a maximum value Z_{max} of the impedance during a heart cycle. Furthermore, the control circuit 14 is arranged to determine a relationship between Z_{min} and Z_{max}. The control circuit 14 is also arranged to vary the time interval ΔT and to monitor the relationship over a plurality of heart cycles. Moreover, the control circuit 14 is arranged to set the time interval ΔT such that the relationship fulfils a predetermined requirement.

The pacer 10 may also be arranged to receive signals indicating the activity level of a living being into which the heart stimulating device 10 is implanted. Such signals can for example be produced by an activity sensor 18 included within the housing 12. Different kinds of activity sensors 18 are known to a person skilled in the art. For example, such an activity sensor may sense the movement of the pacer 10 and thereby the movement of a being carrying the pacer 10. It is also possible to detect the activity of the patient by sensing signals received from different electrodes connected to the pacer 10.

The impedance Z measured between for example the electrodes 32 and 42 depends on the amount of blood in the left ventricle LV. As the amount of blood in the ventricle LV varies during a heart cycle, the measured impedance value Z also varies. Fig 3 illustrates schematically how the impedance value Z may vary with time t over a heart cycle HC. The impedance value Z is low when the ventricle LV is filled with blood. During the systolic phase, when the ventricle LV pumps out the blood, the impedance Z increases to a maximum value Z_{max}, whereafter the impedance value Z is lowered when the ventricle LV fills with blood during the diastolic phase. The control circuit 14 is thus arranged such that Z_{min} and Z_{max} during a heart cycle may be determined. By sensing events in the heart, the control circuit 14 can distinguish different heart cycles from each other.

The difference $Z_{min} - Z_{max}$ is related to the stroke volume of the ventricle LV. The so-called ejection fraction EF is defined as the stroke volume divided by the end diastolic volume. The ejection fraction EF is thus related to $(Z_{min} - Z_{max}) / Z_{min}$. Preferably, we may define the ejection fraction EF as the absolute value in order to always get a value that is larger than zero. The ejection fraction EF is also related to the value of Z_{max} / Z_{min}.

The control circuit is arranged to determine a relationship between Z_{min} and Z_{max}. This relationship can for example be any of the above-described relationships which relate to the stroke volume or the ejection fraction EF. One example of this relationship is the

value of Z_{min} / Z_{max}. The control circuit can be arranged to determine the time interval ΔT such that the ratio Z_{min} / Z_{max} is minimised (or such that its inverse is maximised). The control circuit 14 is thus arranged to set the time interval ΔT such that a predetermined requirement is fulfilled. In this example, the predetermined requirement is thus that Z_{min} / Z_{max} is minimised. By setting ΔT such that the predetermined requirement is fulfilled, the stroke volume, or the ejection fraction EF, is controlled to be as large as possible. The cardiac output is therefore improved. To improve the cardiac output in this manner is important for example for a patient suffering from CHF.

The flow chart of Fig 2 illustrates how the control circuit 14 may be arranged to operate. The flow chart starts by choosing a value for ΔT. This value may for example be a previously set value for ΔT or that $\Delta T = 0$. Stimulating pulses are thereafter delivered to the electrodes (for example to the electrodes 31 and 41) with the time interval ΔT. The impedance value Z is sensed over at least a heart cycle. Z_{min} and Z_{max} are determined. In order to improve the measurement of Z_{min} and Z_{max} it is also possible to sense the impedance variation during several heart cycles before determining Z_{min} and Z_{max}. Z_{min} and Z_{max} may in this case be the average value of Z_{min} and Z_{max}, respectively, over several heart cycles.

Thereafter a relationship between Z_{min} and Z_{max} is determined. As pointed out above, this relationship may for example be Z_{min} / Z_{max}. The value of the determined relationship is stored. A new value for ΔT is set and the previous steps are carried out again in order to determine a new relationship between Z_{min} and Z_{max} and to store also this relationship. The new value for ΔT may be chosen in different manners. It is for example possible to change ΔT in a first direction, for example to increase ΔT with a small amount. The control circuit 14 may then be arranged to monitor whether the relationship Z_{min} / Z_{max} increases or decreases. If this relationship decreases, the time interval ΔT may be further increased and the steps are carried out again in order to determine another relationship between Z_{min} and Z_{max}. On the other hand, in case the ratio Z_{min}

/ Z_{max} were to increase, the time interval ΔT may be changed in the other direction, i.e. according to this example ΔT would then be decreased instead of increased. It should be noted that ΔT can even be negative if it is further decreased. Whether ΔT is positive or negative is thus decisive of which of the two ventricles is first stimulated. The loop illustrated in Fig 2 is carried out a sufficient number of times such that it is possible to determine a ΔT for which the ratio Z_{min} / Z_{max} is as low as possible.

In Fig 4 the ratio Z_{min} / Z_{max} as a function of ΔT is illustrated with a number of points. These points are thus obtained in the manner illustrated in Fig 2 by determining the relationship Z_{min} / Z_{max} for different values of ΔT. The dots illustrated in Fig 4 define a curve in which a minimum can be established. This minimum is in the illustrated figure obtained for ΔT = T1. The control circuit thus determines that at ΔT = T1, the ratio Z_{min} / Z_{max} fulfils the predetermined requirement, i.e. in this example that the ratio is as small as possible. When this has been decided, ΔT is set to be equal to T1. According to a preferred embodiment, the steps illustrated in Fig 2 are carried out when the being into which the pacer 10 is implanted is at rest. This can for example be done at night when the person or animal in question is asleep. As stated above, the pacer 10 may detect the activity level. The control circuit 14 may thus be arranged such that the different steps are carried out when a signal indicates a low level of activity.

Once the time interval ΔT has been determined and set equal to T1, the control circuit 14 may be arranged to carry out a similar determination in order to optimise a value for AV. AV is the so-called AV-delay. This is the time between an atrial sensed or paced event and the delivery of a ventricular output pulse. The AV-delay considered here may for example be the AV-delay for the right part of the heart. As is shown in Fig 5, a certain value for AV is chosen. Thereafter stimulating pulses are delivered with this AV-delay and with the already set time interval ΔT = T1. An impedance value Z is sensed. This impedance value Z can be the same impedance value as illustrated above. Z_{min} and Z_{max} are determined. A relationship between

Z_{min} and Z_{max} is also determined, for example any of the above mentioned relationships. This relationship is stored. A new AV-delay is chosen. This can be done for example in an analogous manner to that according to which the new ΔT was chosen above. The previous steps are then carried out again and a new relationship is determined for the new AV-delay. The different stored relationships are considered together with the corresponding AV-values. A value AV = AV 1 is determined such that the predetermined requirement is fulfilled, for example that the ratio Z_{min} / Z_{max} is as low as possible.

It is also possible to again perform the steps illustrated in Fig 2 to possibly set a new ΔT if this is necessary in order to further improve the cardiac output.

In the embodiment discussed above, the impedance value was sensed between electrodes 31, 32 of the first lead and electrodes 41, 42 of the second lead. However, it is also possible to sense other impedance values in the heart as for example illustrated in the above-disclosed documents. For example, it is possible to sense an impedance value between electrodes 51, 52 of the third lead 50 and electrodes 61, 62 of the fourth lead 60. Such an impedance value may be an indication of the amount of blood in the left atrium LA. It is also possible to use this impedance value in order to control the time interval ΔT and the time interval AV in the same manner as illustrated above.

The heart stimulating device 10 according to the invention thus comprises a housing 12 with the control circuit 14 described above. However, the invention also relates to a heart stimulating system. This system comprises the heart stimulating device 10 and at least a first lead 30 and a second lead 40 connected to the heart stimulating device 10 such that at least two electrodes 31, 41 are connected to the control circuit 14. The system is preferably arranged such that the measured impedance value Z is sensed between an electrode 31 or 32 of the first lead 30 and an electrode 41 or 42 of the second lead 40.

The invention also relates to a manner of using such a heart stimulating system. According to this use, the first lead 30 is arranged such that the first electrode 31 and/or 32 is positioned to stimulate a first ventricle RV of a heart and the second lead 40 is arranged such that the second electrode 41 and/or 42 is positioned to stimulate the second ventricle LV of the heart. According to his manner of using the device the above-illustrated steps are carried out.

The leads are preferably arranged such that the impedance value Z is measured across at least a part of one of said ventricles RV, LV, preferably across at least part of the left ventricle LV as has been discussed above. Alternatively, or additionally, electrodes 61, 62 and 51, 52 may be arranged such that an impedance value is sensed also across at least a part of the left atrium LA of the heart.

The invention is not limited to the described embodiments but may be varied and modified within the scope of the following claims.

Claims

1. An implantable heart stimulating device (10) comprising:

a housing (12)

a control circuit (14) arranged in said housing (12), the control circuit (14) being adapted to be connected to a first electrode (31, 32) to be positioned to stimulate a first ventricle (RV) of the heart,

said control circuit also being adapted to be connected to at least a second electrode (41, 42) to be positioned to stimulate the second ventricle (LV) of the heart,

said control circuit (14) being arranged to at least enable the following:

a) delivering electrical stimulating pulses to said first (31, 32) and second (41, 42) electrodes in order to stimulate the first (RV) and second (LV) ventricles, respectively, the control circuit (14) being arranged to enable the delivery of the said stimulating pulses to said first (31, 32) and second (41, 42) electrodes within the same cycle of the heart such that there is a time interval (ΔT) between them, the control circuit (14) being arranged such that said time interval (ΔT) is variable,

b) sensing signals receivable from electrodes (41, 42, 31, 32, 51, 52, 61, 62) positionable at two different positions in the heart,

c) deriving an impedance value (Z) based on said sensed signals, said impedance value being indicative of the impedance between said electrodes positionable at two different positions in the heart,

d) determining a minimum value (Z_{min}) and a maximum value (Z_{max}) of said impedance value during a heart cycle,

e) determining a relationship between said minimum and maximum values,

f) varying said time interval (ΔT) and monitoring said relationship over a plurality of heart cycles,

g) setting said time interval (ΔT) such that said relationship fulfils a predetermined requirement.

2. An implantable heart stimulating device (10) according to claim 1, wherein said control circuit (14) is arranged such that said relationship comprises the ratio between said minimum value (Z_{min}) and said maximum value (Z_{max}).

3. An implantable heart stimulating device (10) according to claim 1, wherein said control circuit (14) is arranged such that said relationship comprises the difference between said minimum value (Z_{min}) and said maximum value (Z_{max}).

4. An implantable heart stimulating device (10) according to claim 3, wherein said control circuit (14) is arranged such that said relationship comprises the ratio between said minimum value (Z_{min}) and the difference between said minimum value (Z_{min}) and said maximum value (Z_{max}).

5 An implantable heart stimulating device (10) according to claim 2 or 4, wherein said predetermined requirement is that said ratio is minimized.

6. An implantable heart stimulating device (10) according to claim 5, wherein said control circuit (14) is arranged such that said time interval (ΔT) is changed in a first direction, said first direction being either an increase or a decrease of said time interval (ΔT), wherein the control circuit (14) is arranged to monitor the change of said ratio when said time interval (ΔT) is changed in said first direction, wherein, if said ratio decreases, said time interval (ΔT) is further changed in said first direction until said predetermined requirement has been established.

7. An implantable heart stimulating device (10) according to claim 6, wherein the control circuit (14) is arranged such that if said ratio increases, said time interval (ΔT) is changed in the opposite direction to said first direction, whereafter said time interval (ΔT) is further changed in said opposite direction until said predetermined requirement has been established.

8. An implantable heart stimulating device (10) according to any of the preceding claims, wherein said control circuit (14) is arranged also to enable the reception of signals indicating the activity level of a living being into which the heart stimulating device (10) is implanted, wherein the control circuit (14) is arranged such that at least the steps f) and g) are performed at a time when said signals indicate a low level of activity.

9. An implantable heart stimulating device (10) according to any of the preceding claims, wherein said control circuit (14) is arranged to enable the delivery of stimulating pulses in which at least one atrio-ventricular delay (AV) is controllable, wherein said control circuit (14) is arranged to keep said time interval (ΔT) at said set value and to:

h) vary said atrio-ventricular delay (AV) and to thereby monitor said relationship over a plurality of heart cycles,

i) set said atrio-ventricular delay (AV) such that said relationship fulfils said predetermined requirement.

10. An implantable heart stimulating device (10) according to any of the preceding claims, wherein the heart stimulating device (10) is arranged such that said control circuit (14) is arranged to be connected to a first lead (30) comprising said first electrode (31, 32) and a second lead (40) comprising said second electrode (41, 42), wherein said control circuit (14) is arranged such that said sensed signals, receivable from electrodes (31, 32; 41, 42) positioned at two different positions, are received via said first (30) and second (40) leads, respectively.

11. A heart stimulating system comprising a heart stimulating device (10) according to any of the preceding claims and a first lead (30) comprising at least said first electrode (31, 32) and a second lead (40) comprising at least said second electrode (41, 42), wherein said first (30) and second (40) leads are connected to the heart stimulating device (10) such that said first (31, 32) and second (41, 42) electrodes are connected to said control circuit (14).

12. A heart stimulating system according to claim 11, wherein said system is arranged such that said impedance value (Z) is sensed between an electrode (31, 32) of said first lead (30) and an electrode (41, 42) of said second lead (40).

13. A manner of using a heart stimulating system according to claim 11 or 12, wherein said first electrode (31, 32) is positioned to stimulate a first ventricle (RV) of a heart of a human or animal being and said second electrode (41, 42) is positioned to stimulate the second ventricle (LV) of said heart and wherein the steps a) to g) are performed.

14. A manner according to claim 13, wherein the system is arranged such that said impedance value (Z) is sensed between two electrodes (31, 32; 41, 42) positioned such that the impedance value (Z) is measured across at least a part of one of said first (RV) and second ventricles (LV).

15. A manner according to claim 14, wherein said ventricle, across which the impedance value (Z) is measured, is the left ventricle (LV) of the heart.

16. A manner according to any of the claims 13-15, wherein the system is arranged such that an impedance value (Z) is sensed across at least a part of the left atrium (LA) of said heart.

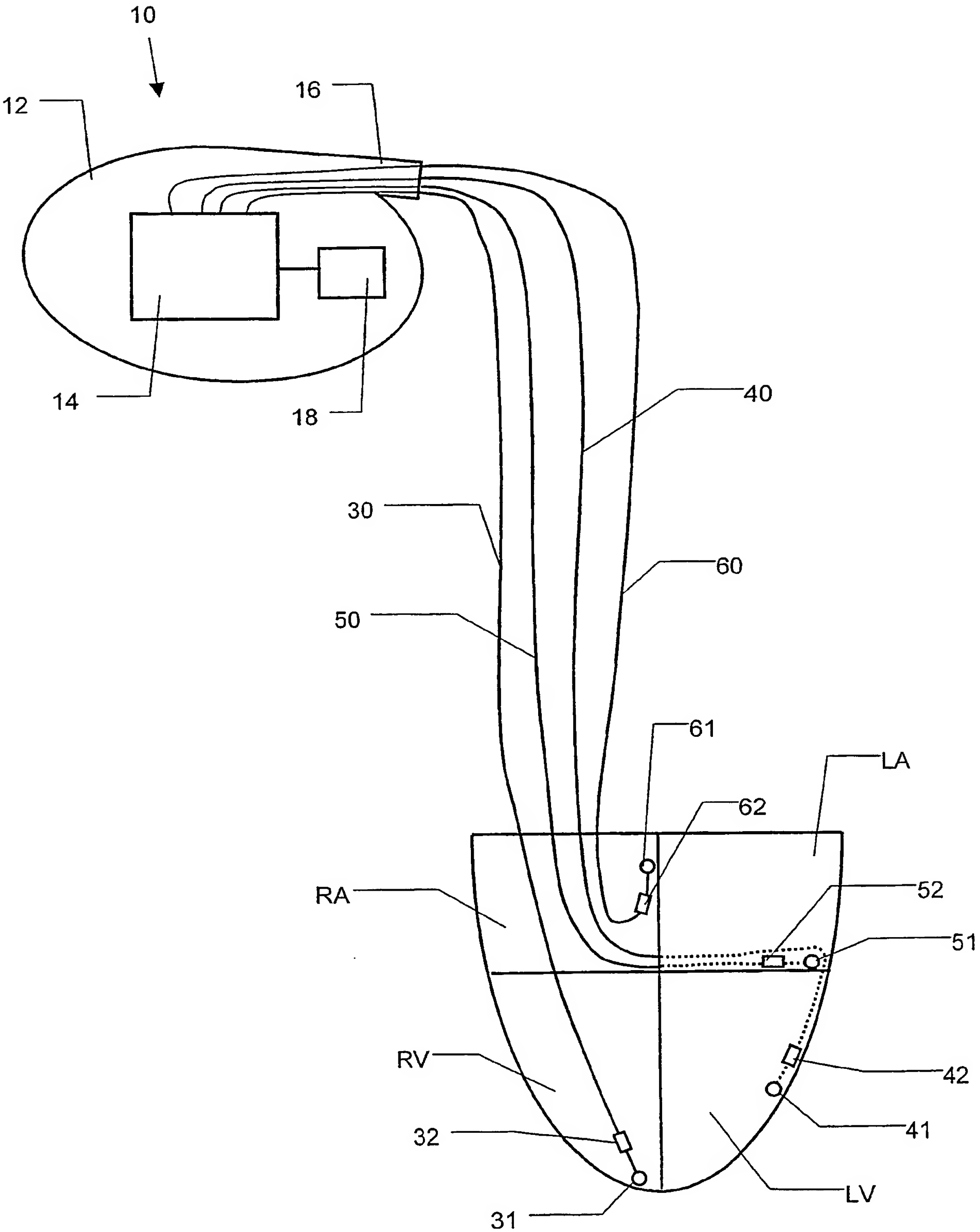

FIG 1

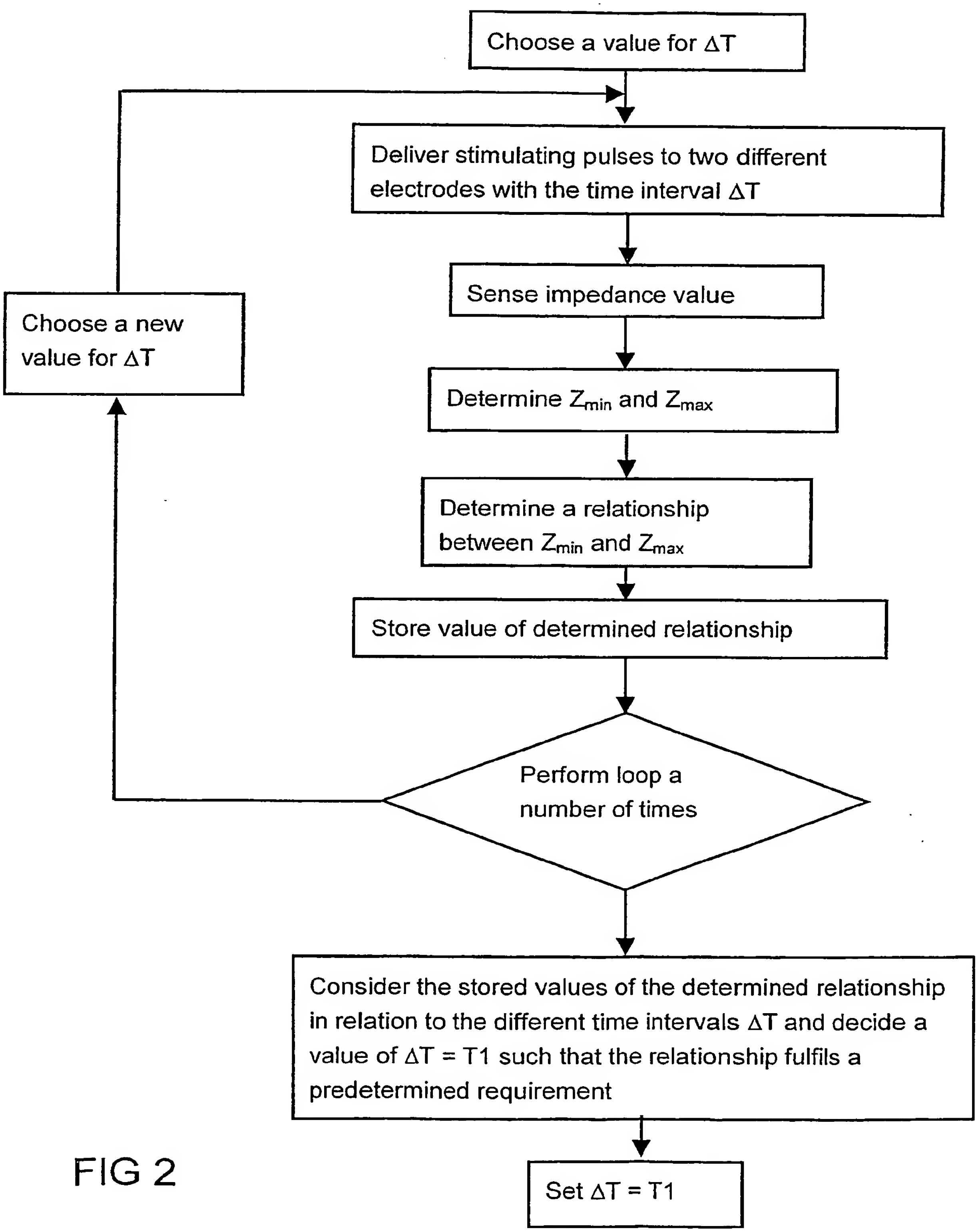
Choose a value for ΔT
Deliver stimulating pulses to two different electrodes with the time interval ΔT
Sense impedance value
Determine Z_{min} and Z_{max}
Determine a relationship between Z_{min} and Z_{max}
Store value of determined relationship
Perform loop a number of times
Choose a new value for ΔT
Consider the stored values of the determined relationship in relation to the different time intervals ΔT and decide a value of ΔT = T1 such that the relationship fulfils a predetermined requirement
Set ΔT = T1

FIG 2

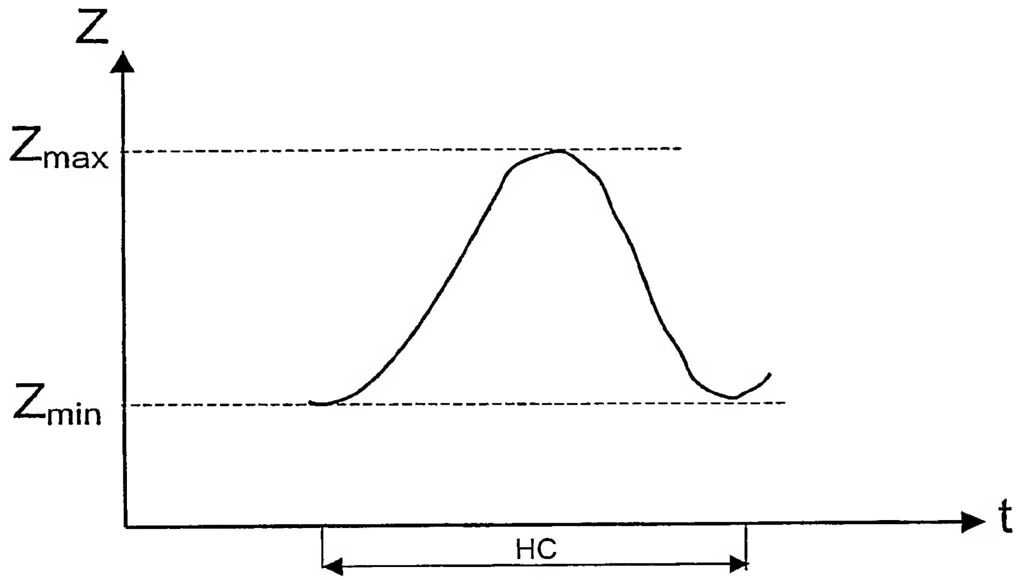

FIG 3

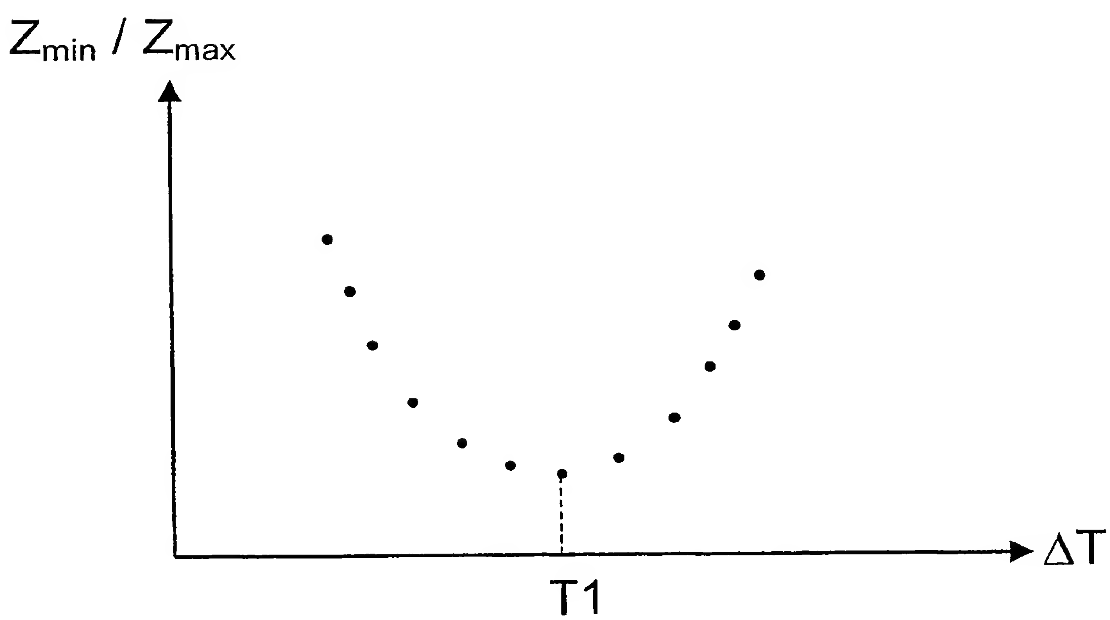

FIG 4

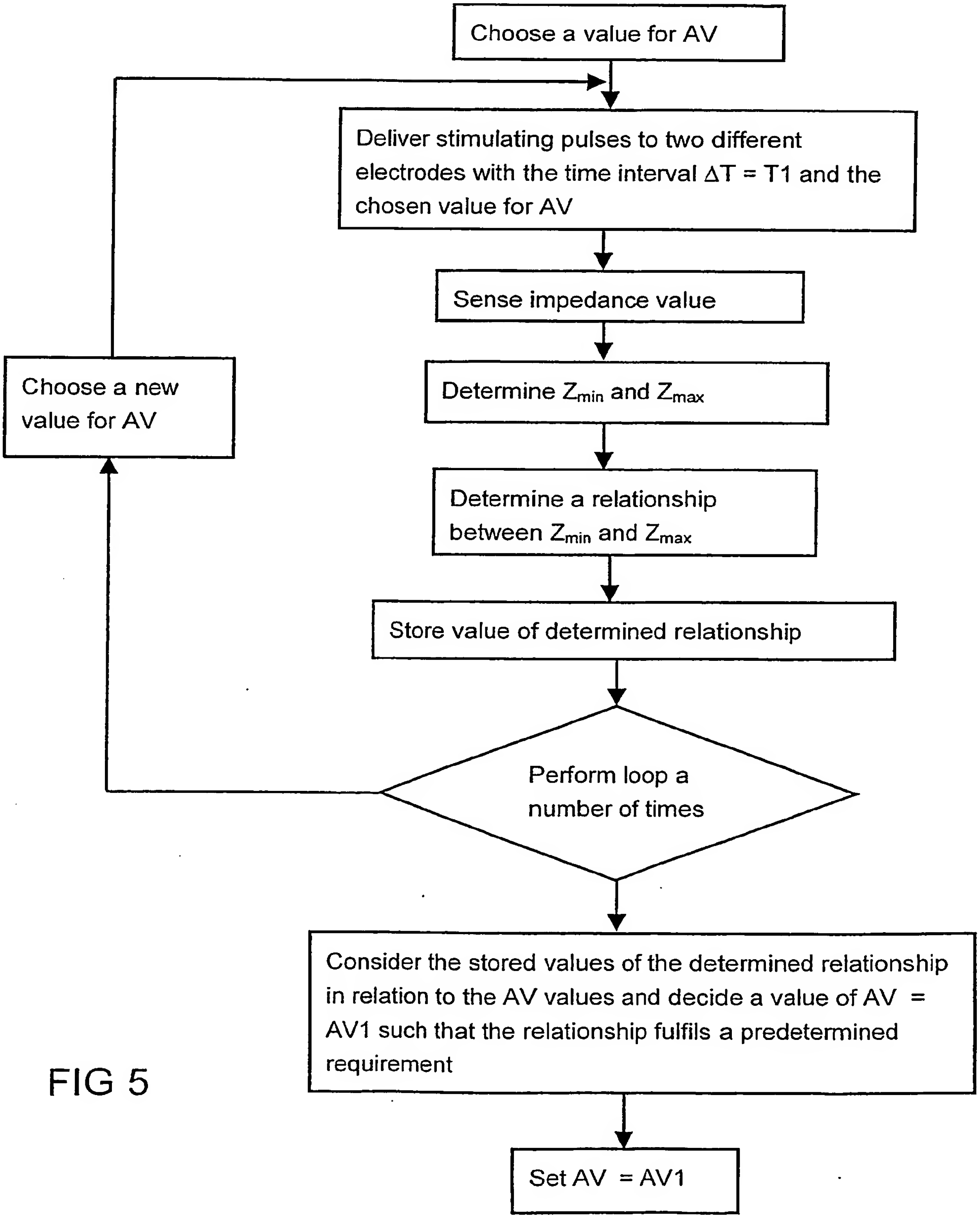
Choose a value for AV
Deliver stimulating pulses to two different electrodes with the time interval ΔT = T1 and the chosen value for AV
Sense impedance value
Determine Z_{min} and Z_{max}
Determine a relationship between Z_{min} and Z_{max}
Store value of determined relationship
Perform loop a number of times
Choose a new value for AV
Consider the stored values of the determined relationship in relation to the AV values and decide a value of AV = AV1 such that the relationship fulfils a predetermined requirement
Set AV = AV1

FIG 5

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 02/01817

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61N 1/368, A61B 5/053

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: A61N, A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-INTERNAL, WPI DATA, INSPEC, MEDLINE, BIOSIS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2001049543 A1 (KROLL), 6 December 2001 (06.12.01), see the whole document, particularly: fig. 1,9,10, piece 7, 12, 21-27, 69 and 90-93 --	1-16
X	US 2001034540 A1 (MOLIN), 25 October 2001 (25.10.01), see the whole document, particularly piece 6-12 and 19-34 --	1-16
X	US 2001012953 A1 (MOLIN ET AL), 9 August 2001 (09.08.01), see the whole document, particularly piece 10 and 21-24, cited in the application --	1-16

[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

* Special categories of cited documents:

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"E" earlier application or patent but published on or after the international filing date

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"O" document referring to an oral disclosure, use, exhibition or other means

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"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

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"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
18 December 2002	08 -01- 2003

Name and mailing address of the ISA/	Authorized officer
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C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 6070100 A (BAKELS ET AL), 30 May 2000 (30.05.00), cited in the application --	1-16
A	US 5154171 A (CHIRIFE), 13 October 1992 (13.10.92), abstract, column 6, line 67 - column 7, line 30, cited in the application --	1-16
A	US 4686987 A (SALO ET AL), 18 August 1987 (18.08.87), abstract, column 1, line 30 - column 2, line 58, fig. 1-3, claims 1-2 -- --------	1-16

INTERNATIONAL SEARCH REPORT
Information on patent family members

01/12/02

International application No.
PCT/SE 02/01817

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2001049543 A1	06/12/01	EP 1155711 A	21/11/01
US 2001034540 A1	25/10/01	AU 1869701 A	04/06/01
		BR 0015756 A	16/07/02
		EP 1138346 A	04/10/01
		EP 1255702 A	13/11/02
		FR 2806311 A,B	21/09/01
		NO 20022394 A	21/05/02
US 2001012953 A1	09/08/01	EP 1108446 A	20/06/01
		FR 2802433 A,B	22/06/01
		JP 2001198228 A	24/07/01
US 6070100 A	30/05/00	AU 1714499 A	05/07/99
		EP 1039951 A	04/10/00
		US 6219579 B	17/04/01
		US 6223079 B	24/04/01
		US 6223082 B	24/04/01
		US 6238420 B	29/05/01
		US 2001010009 A	26/07/01
		WO 9930777 A	24/06/99
US 5154171 A	13/10/92	AT 139708 T	15/07/96
		CA 2065973 A,C	16/12/92
		DE 69211793 D,T	31/10/96
		EP 0532148 A,B	17/03/93
		SE 0532148 T3	
		ES 2088833 T	01/10/96
		GR 94300094 T	31/01/95
		JP 7171218 A	11/07/95
US 4686987 A	18/08/87	DE 3750983 D,T	18/05/95
		EP 0288630 A,B	02/11/88
		US 5190035 A	02/03/93